



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply.

EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

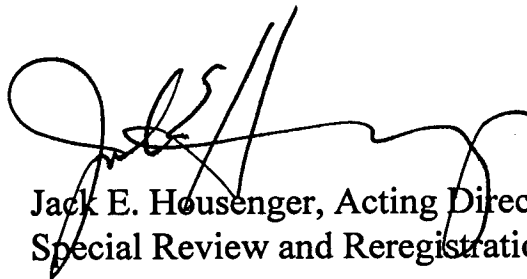
The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

A handwritten signature in black ink, appearing to read 'J. Housenger', is written over the typed name and title.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 8, 1999

MEMORANDUM

SUBJECT: CHLORPYRIFOS-METHYL. Product and Residue Chemistry
Chapters of RED. Chemical Number 059102. DP Barcode
D256666.

FROM: Sarah Law, Chemist
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

THRU: Steven A. Knizner, Branch Senior Scientist
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

TO: Mark Hartman, Chemical Review Manager
Special Review and Reregistration Division (7508C)

Attached please find the product and residue chemistry chapters
for chlorpyrifos-methyl.

CHLORPYRIFOS-METHYL
PC Code 059102

Reregistration Eligibility Decision
Residue Chemistry Considerations

May 11, 1999

Contract No. 68-D4-0010

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA

Submitted by:
Dynamac Corporation
1910 Sedwick Road
Building 100, Suite B
Durham, NC 27713

CHLORPYRIFOS-METHYL

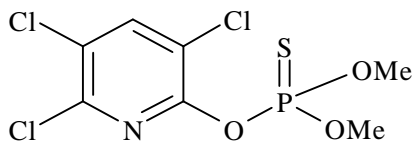
REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code 059102

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Chlorpyrifos-methyl



REREGISTRATION ELIGIBILITY DOCUMENT

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code 059102

INTRODUCTION

Chlorpyrifos-methyl (CPM) [*O,O*-dimethyl-*O*-(3,5,6-trichloro-2-pyridyl)phosphorothioate] is an insecticide registered for use on stored grain crops including barley, oats, rice, sorghum, and wheat. CPM is manufactured by DowElanco under the trade name Reldan®. CPM formulations registered to DowElanco for use on food/feed crops include one emulsifiable concentrate (EC) formulation. Application of this product is limited to post-harvest treatment of stored grains or grain storage facilities.

REGULATORY BACKGROUND

CPM has been the subject of a petition (PP#0F2423 and FAP#0H5277) proposing tolerances for residues in/on stored grains and livestock commodities that was recommended for approval on April 30, 1985; all current CPM tolerances are based upon this petition. In addition, there is currently one active petition pending (PP#6F3429/6H5506) from DowElanco pertaining to use of CPM on stored corn grain. This petition is currently in reject status based upon deficiencies in label directions and proposed tolerances (DP Barcode D186441, J. Morales, 6/2/93 and DP Barcode D200683, M. Flood, 6/15/94). The information contained in this reregistration eligibility document (RED) Chapter outlines the current Residue Chemistry Science Assessments with respect to the reregistration of CPM.

Tolerances have been established for residues of CPM and its metabolite 3,5,6-trichloro-2-pyridinol (TCP) in/on barley, oats, rice, sorghum, and wheat grain at 6.0 ppm; tolerances for milled fractions (excluding flour) of each of these raw agricultural commodities (RACs) have been established at 30 ppm (rice and wheat), 90 ppm (barley and sorghum), and 130 ppm (oats) under 40 CFR §185.1050 and §186.1050. Tolerances have also been established for residues of CPM in milk and milk fat at 0.05 and 1.25 ppm, respectively, eggs at 0.1 ppm, and in meat, meat-by-products (mbyp) and fat of cattle, goats, hogs, horses, poultry and sheep at 0.5 ppm [§180.419]. During the reregistration of chlorpyrifos, the Agency determined that the metabolite TCP, common to both chlorpyrifos and CPM, is no longer considered to be of toxicological concern (E.

Doyle, TOX Branch memo dated 4/1/91); HED recommended the removal of TCP from the tolerance expression for CPM (PP#6F3429/6H5506, DEB No. 6969, M. Flood, 4/29/91). Therefore, tolerances for residues in/on plant and animal commodities are to be expressed in terms of parent CPM only.

The Agency has updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1, OPPTS 860.1000). As a result of changes to Table 1, additional CPM residue data are now required for some commodities; these data requirements have been incorporated into this document. These new data requirements will be imposed at the issuance of the CPM RED but should not impinge on the reregistration eligibility decisions for CPM. The need for revisions to dietary exposure/risk assessments will be determined upon receipt of the required residue chemistry data.

SUMMARY OF SCIENCE FINDINGS

OPPTS GLN 860.1200: Directions for Use

A search of the Agency's Reference Files System (REFS) on 4/16/99 indicated that there is one CPM end-use product (EP) registered to DowElanco with uses on food/feed crops. This EP label (Reldan[®] 4E, EPA Reg. No. 62719-43, accepted 2/99) is for a 4 lb/gal EC that may be applied as a coarse spray to a moving stream of grain at 3-6 ppm in 1-5 gallons of water or food grade mineral oils per 1000 bushels of grain; the label specifies that the high dose is used only when grain is stored ≥ 3 months. The label also permits the application of a 1% solution of CPM to the walls and floors of grain bins and warehouses prior to grain storage at a rate of 0.04 lb ai/650-1250 ft² diluted in one gallon of water. The number of applications allowed over the entire storage period is not specified.

A review of the EP label and supporting residue data indicate that the following label amendments are required:

- ! The label should be amended to specify that a maximum number of one application to stored grain commodities is permitted during the entire storage period.
- ! The label must be revised to require pretreatment testing of grain samples to verify that the grain has not been treated previously with CPM.

A tabular summary of the residue chemistry science assessments for reregistration of CPM is presented in Table A. The conclusions listed in Table A regarding the reregistration eligibility of CPM food/feed uses are based on the use patterns registered by the basic producer, DowElanco. When end-use product data call in's (DCIs) are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer's (DowElanco's) labels.

OPPTS GLN 860.1300: Nature of the Residue in Plants

The qualitative nature of the residue in plants is adequately understood based on metabolism studies conducted on stored corn and wheat grain. HED had previously determined that TCP is no longer a residue of concern with respect to chlorpyrifos because of its inactivity as a cholinesterase inhibitor (E. Doyle, 4/1/91). Therefore, HED concluded that TCP need not appear in the tolerance expression, and that tolerances are to be expressed in terms of CPM *per se* (M. Flood, 4/29/91).

In the metabolism studies, corn and wheat were treated with ^{14}C -CPM to give a concentration of 32.4 ppm on the grain. Parent compound comprised >80% of the initial dose of ^{14}C -activity found on the day of treatment, and 19.1-62.3% in grain stored 30-180 days. Parent decreased with time with a corresponding increase in the major metabolites, TCP and the monoacid of CPM, which accounted for up to 31.2% and 19.7% of the initial ^{14}C -dose, respectively, in grains after 180 days of storage. Based upon the plant metabolism data, the phosphate ester undergoes extensive hydrolysis yielding products that are expected to have little or no cholinesterase inhibiting activity. Minor amounts ($\leq 0.6\%$ of the initial dose) of the S-methyl isomer were also detected.

OPPTS GLN 860.1300: Nature of the Residue in Livestock

The qualitative nature of CPM residues in animals is adequately understood based upon acceptable ruminant and poultry metabolism studies. HED has determined that the CPM residues to be regulated in animal commodities will include CPM only.

In goat liver, kidney, and heart, the major residue was TCP which comprised 66.4-75.1% of the total radioactive residue (TRR); parent accounted for up to 2.9% of the TRR. In fat and milkfat, parent was the major component, accounting for 49-74%. The major terminal residues in poultry tissues and egg yolks were parent, TCP, and the monoacid. TCP and the monoacid accounted for 67.1 and 22.6% of the TRR in kidney, and up to 20.3 and 26.7% of the TRR in egg yolk, respectively. Parent was the principle residue in fat (74.8% TRR) and accounted for ~16% of the TRR in egg yolk. Minor amounts of the S-methyl isomer were also detected in animal tissues and milk.

OPPTS GLN 860.1340/1360: Residue Analytical Methods/Multiresidue Methods

The Pesticide Analytical Manual (PAM) Vol. II lists a GC/ECD method (Method I) that determines the combined residues of CPM and TCP in or on stored grain commodities following conversion of CPM to TCP *via* hydrolysis; residues of TCP are then derivatized prior to GC analysis. This method is not ideal for enforcement purposes because it is not capable of specifically determining residues of CPM *per se*; combined residues of CPM and TCP are measured.

However, adequate methodology is available to enforce tolerances for residues in/on plant commodities: The FDA PESTDATA database (PAM Vol. I, January 1994) indicates that CPM is completely recovered using FDA Multiresidue Protocols D and E (PAM I Sections 232.4 and 211.1). Residue data on stored grains and grain processed commodities were collected using adequate analytical methods (Methods ACR 78.18 and ACR 77.6(3), respectively) capable of determining CPM *per se*. The registrant should conduct an independent laboratory validation (ILV) for one of these methods and submit results to the Agency. The Agency will then conduct a tolerance method validation (TMV).

Briefly, residues in/on whole grains are extracted by shaking with acetone, centrifuged, diluted, and analyzed by GC using a flame photometric detector (FPD); the validated LOQ for residues of CPM in/on whole grains is 1.0 ppm. Residues in processed fractions are extracted in the same manner, partitioned sequentially with hexane and acetonitrile (ACN), concentrated to remove the ACN, and redissolved in hexane. The residues are further purified on a silica gel column prior to analysis by GC/FPD. The method was validated using grain processed fractions (wheat grain, flour, and bran) to a lower limit of 0.01 ppm.

The GC/FPD method listed in PAM Vol. II (Method II) capable of determining residues of CPM *per se* in meat, milk, and eggs of livestock is adequate for enforcement of tolerances on animal commodities.

Data on residues of CPM *per se* in animal commodities have been collected using an adequate GC/FPD method (Method ACR 77.6.1) currently published in PAM II as Method II. Briefly, residues in muscle, liver, and kidney are extracted with acetone, filtered, concentrated, and partitioned into hexane; residues in fat are extracted with hexane. The residues are then partitioned with ACN, concentrated, redissolved in hexane, and cleaned-up on a silica gel column prior to analysis by GC/FPD. Using a modification of this method (Method ACR 77.6.s1), residues in milk or cream are heated to 45 C, extracted with a solution of methanol:hexane (1:1, v/v) and NaCl, and centrifuged. The residues are then purified and analyzed as described above for tissues. The method was validated by the registrant to a lower limit of 0.01 ppm using tissues and milk; however, as the Agency validated the method to a lower limit of 0.05 ppm, tolerances have been reassessed at 0.05 ppm.

The Agency previously concluded (DP Barcode D169228, J. Morales, 4/30/92) that residues on stored corn grain could not practically be controlled by use label restrictions because stored grain can be moved from one location to another and treated at each location. To address the potential for over-tolerance residues resulting from multiple postharvest grain treatments using CPM, Gustafson has developed an immunoassay procedure to be used in grain storage areas to verify that grain has not been previously treated. The method, which can rapidly detect residues in excess of 0.1 ppm, was independently validated (DP Barcode D193346, M. Flood, 3/10/94) and has been successfully validated by the Agency's Analytical Chemistry Branch (DP Barcode D200683, M. Flood, 6/15/94). This method cannot be substituted for the Agency-validated,

conventional analytical method required for enforcement purposes, but is suitable for pre-treatment testing.

Residue data for TCP in/on stored grains and livestock commodities are also available and were collected using adequate methodology. However, as TCP is no longer a residue of concern, these methods are not presented.

OPPTS GLN 860.1380: Storage Stability Data

Adequate storage stability data are available for the purposes of risk assessment. Although no storage stability data were submitted to support the residue studies, the existing storage stability data for chlorpyrifos suggest that residues of CPM are stable frozen in stored plant and animal matrices. The Residue Chemistry Chapter of the Chlorpyrifos Reregistration Standard (2/29/84) indicates that residues of chlorpyrifos are relatively stable (65-110% of the original fortification levels) in corn and sorghum matrices stored at -18 C for up to 27 months; likewise, residues of chlorpyrifos *per se* are stable (69-74% of the initial levels) in livestock commodities stored frozen for ~4 years. Confirmatory storage stability data on CPM are needed to confirm these assumptions.

As sample storage intervals were not reported in the magnitude of the residue studies, detailed sample histories should be submitted along with the required storage stability data. The petitioner reported that samples of plant and animal material were maintained frozen from collection to analysis.

OPPTS GLN 860.1500: Magnitude of the Residue in Crop Plants

Sufficient residue data are available on stored grain crops (barley, oats, rice, sorghum, and wheat) for the purposes of risk assessment. However, deficiencies in label use directions and storage stability need to be resolved, and confirmatory data supporting the residue studies on stored grains are required.

The available data are from a 1979 residue study in which samples of barley, corn, oat, rice, sorghum, and wheat grain were treated with CPM once at 6 ppm (1x rate) and analyzed for residues of CPM immediately following treatment and after storage intervals of 0 (up to 50 days posttreatment), 1, 3, 6, and 12 months. Residues of CPM *per se* were 4.3-7.0 ppm in/on one sample each of barley (5.4 ppm), corn (4.3 ppm), oats (5.2 ppm), rice (7.0 ppm), and wheat (5.5 ppm) grain analyzed immediately after treatment. [HED notes that the rice residue value of 7.0 ppm is above the 1 X application rate (would be considered a violative sample, therefore, the rice HAFT that will be used is 6.0 ppm)]

Data are needed from three studies depicting residues of CPM in/on treated wheat grain stored in CPM-treated storage facilities and sampled on the day of treatment following applications at the maximum use rate. The trials should include the use of both water and mineral oil as the spray

diluent. The current labels allow treatment of storage facilities prior to storage of treated grain, and data reflecting this potential “worse-case” scenario were not provided by the original residue studies.

OPPTS GLN 860.1500: Magnitude of the Residue in Crop Plants - Pending Petitions

There is currently one active petition pending from DowElanco pertaining to use of CPM on stored corn grain (PP#6F3429/6H5506). This petition is currently in reject status based upon deficiencies in label directions and proposed tolerances (DP Barcode D186441, J. Morales, 6/2/93 and DP Barcode D200683, M. Flood, 6/15/94).

OPPTS GLN 860.1520: Magnitude of the Residue in Processed Food/Feed

Pending resolution of storage stability issues, the reregistration requirements for magnitude of CPM residues in processed food/feed commodities are fulfilled for stored grain commodities.

Currently, tolerances are established for the combined residues of CPM and TCP in milled fractions (exc. flour) of barley, oats, rice, sorghum, and wheat at 30-120 ppm. These tolerances were determined based on the proposed tolerances for the grain (6.0 ppm) and the highest concentration factor found for the combined residues in any processed grain fraction. In the following reassessment, tolerances were determined using the concentration factor for residues in each regulated processed commodity and the highest average field trial (HAFT) residues for the specified grain. The HAFT residues for parent are from the 1979 study on stored grains in which one sample of each grain commodity was analyzed immediately following one treatment with CPM at 6.0 ppm.

The available processing study on barley does not provide residue data on pearled barley, flour, or bran; however, data from the wheat processing study are translatable to barley. Based on HAFT residues of 5.4 ppm in barley grain, and a concentration factor of 2.1x for bran, a tolerance for residues of CPM *per se* should be established in barley bran at 15 ppm.

The available study on oats indicates that residues of CPM *per se* concentrate by 2.5x in hulls, but do not concentrate in groats. Based on a 2.5x concentration factor and HAFT residues of 5.2 ppm for stored oat grain, a tolerance of 15 ppm should be established for residues of CPM *per se* in oat hulls. Data on oat flour are not available; however, the wheat processing study indicates that residues of CPM *per se* do not concentrate in flour.

The available rice processing study indicates that residues of CPM *per se* concentrate on average in hulls by 3.6x, and in bran by 1.8x, but do not concentrate in polished rice. Tolerances for residues of CPM *per se* should be established at 25 ppm in hulls and 15 ppm in bran based on the concentration factors and HAFT residues of 6.0 ppm.

The available wheat processing study indicates that residues of CPM *per se* concentrate in bran (2.1x), shorts (3.2x), reddog (1.5x), and germ (2.7x), but do not concentrate in flour. Based on the concentration factors and HAFT residues of 5.5 ppm, the tolerance for residues of CPM in wheat milled fractions (exc. flour) should be lowered to 20 ppm.

When separate tolerances are established for the appropriate processed commodities, the tolerance for CPM residues in barley, oats, and rice milled fractions should be revoked.

Flour is the only sorghum processed commodity currently regulated; however, OPPTS.GLN 860.1000 (Table 1) indicates that residue data on sorghum flour are not needed at this time as it is used exclusively in the U.S. as a component for drywall, and not as either a human food or livestock feed. In addition, the sorghum processing study demonstrated that residues of CPM do not concentrate appreciably (1.4x) in sorghum flour. The tolerance for residues of CPM in milled fractions of sorghum (excluding flour) should be revoked.

Data from the corn processing study indicate that CPM residues in/on corn aspirated grain fractions are 84x higher than in/on corn grain (PP#6F3429, DP Barcode D169228, J Morales, 4/30/92). Additional data depicting the potential for concentration of CPM residues in/on aspirated grain fractions derived from sorghum and wheat are required.

OPPTS GLN 860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

Reregistration requirements for magnitude of the residue in meat, milk, poultry, and eggs are fulfilled. Adequate poultry, ruminant, and swine feeding studies are available depicting residues of CPM *per se* in meat, milk, poultry and eggs. Based upon the anticipated residues of the RACs, the *acute* and *chronic* calculated dietary burdens for livestock are 1.3 ppm for beef and dairy cattle, 1.1 ppm for hogs, and 0.05 ppm for poultry and are presented in Table #1.

The tolerance determined for aspirated grain fractions (AGF) will have a substantial impact on the dietary burden. A tolerance of at least 400 ppm, used in calculating the dietary burdens shown below, will be required for CPM residues in/on AGF, based upon the 84x concentration factor and HAFT residues of 4.3 ppm in corn grain. However, this tolerance cannot be assessed until AGF data are available on wheat and sorghum. If significantly higher residues are found in wheat or sorghum aspirated grain fractions, a new feeding study may be required. Note that the available processing study on oats indicates that CPM residues concentrate by 16x in oat dust.

Table #1. Calculation of acute and chronic dietary burdens of livestock animals for CPM.

| Feed Commodity | % Dry Matter ^a | % Diet ^a | Anticipated Residue (ppm) ^b | Acute Dietary Contribution (ppm) ^c | Chronic Dietary Contribution (ppm) ^d |
|------------------------------|---------------------------|---------------------|--|---|---|
| Beef and Dairy Cattle | | | | | |
| wheat grain | 89 | 20 | 0.06 | 0.013 | 0.013 |
| corn forage | 88 | 60 | 0 | 0 | 0 |
| aspirated grain fractions | 85 | 20 | 5.04 | 1.19 | 1.19 |
| TOTAL BURDEN | | 100 | | 1.3 | 1.3 |
| Poultry | | | | | |
| wheat grain | N/A | 80 | 0.06 | 0.048 | 0.048 |
| soybean meal | N/A | 20 | 0 | 0 | 0 |
| TOTAL BURDEN | | 100 | | 0.05 | 0.05 |
| Swine | | | | | |
| wheat grain | N/A | 80 | 0.06 | 0.048 | 0.048 |
| aspirated grain fractions | N/A | 20 | 5.04 | 1.01 | 1.01 |
| TOTAL BURDEN | | 100 | | 1.1 | 1.1 |

^a Table 1 (OPPTS.GLN 860.1000).^b RAC anticipated residue (AR) according to Table # 6. The AR for aspirated grain fractions = RAC AR (0.06 ppm) * Concentration Factor (84x).^c Acute Dietary Contribution = [tolerance / % DM (if cattle)] X % diet).^d Chronic Dietary Contribution = [tolerance / % DM (if cattle)] X % diet).

In the ruminant feeding study, at a feeding level of 100 ppm (~ 77 x), uncorrected residues of CPM in beef tissues and milk were as follows: muscle and liver (<0.01 ppm), kidney (0.03 ppm), fat (0.61 ppm) and cream (0.40 ppm, reflecting 0.03 ppm in whole milk). These data indicate that the tolerances for residues of CPM *per se* in cattle, goats, horses, and sheep should be lowered to 0.05 ppm for muscle and meat byproducts, and increased to 1.0 ppm for fat; the tolerances for residues in milkfat and milk, 1.25 ppm for milkfat (reflecting 0.05 ppm in whole milk), are adequate. Table 2 summarizes the ruminant ARs to be used for meat, meat byproducts, meat fat and milk in the acute and chronic dietary exposure analysis.

Table # 2. Maximum Acute and Chronic Anticipated Residue (AR) Values [at 100 pm (77 X) extrapolated to (1 X)] in Ruminant Tissues.

| TISSUE | ACUTE and CHRONIC ARs ^a |
|--------------|------------------------------------|
| Muscle | 0.0001 |
| Liver | 0.0001 |
| Kidney | 0.0004 |
| Fat | 0.008 |
| Milk Fat | 0.005 |
| Milk (whole) | 0.0004 |

^a Acute and Chronic AR = Study Residue Value (ppm) / 77 X.

In the hog feeding study, at a feeding level of 100 ppm (~ 1.2 x), residues of CPM were 0.13 ppm in muscle, <0.01 ppm in liver and kidney, and 0.74 ppm in fat. These data indicate that the tolerance for residues in fat should be increased to 1.0 ppm, and that the tolerances for residues in meat and mbyp should be lowered to 0.15 ppm and 0.05 ppm, respectively. Table 3 summarizes the hog ARs to be used for meat, meat byproducts and meat fat in the acute and chronic dietary exposure analysis.

Table # 3. Maximum Acute and Chronic AR Values [at 100 pm (91 X) extrapolated to (1 X)] in Hog Tissues.

| TISSUE | ACUTE and CHRONIC ARs ^a |
|--------|------------------------------------|
| Muscle | 0.001 |
| Liver | 0.00009 |
| Kidney | 0.00003 |
| Fat | 0.007 |

^a Acute and Chronic AR = Study Residue Value (ppm) / 91 X.

In the poultry feeding study, hens were dosed with CPM at 0, 10 (200 x), 30 (600 x) or 100 (2000 x) ppm. At the 10 ppm dose, residue levels were <0.01 ppm in muscle, liver, fat and eggs. At the 30 ppm dose, residue levels were < 0.01 ppm in muscle, liver and eggs; in fat the residue level was 0.01 ppm. At the 100 ppm dose, residue levels were 0.01 ppm in muscle, <0.01 ppm in liver, 0.08 ppm in fat and 0.02 ppm in eggs. Based on these data, the established tolerances for residues of CPM in poultry should be lowered to 0.01 ppm in muscle, mbyp, and eggs, and 0.05 ppm in fat. Table 4 summarizes the poultry ARs to be used for meat, meat byproducts, meat fat and eggs in the acute and chronic dietary exposure analysis.

Table # 4. Maximum Acute and Chronic AR Values [at 100 pm (2000 X) extrapolated to (1 X)] in Poultry Tissues.

| TISSUE | ACUTE AR ^a |
|--------|-----------------------|
| Muscle | 0.000005 |
| Liver | 0.000005 |
| Fat | 0.00004 |
| Eggs | 0.00001 |

^a Acute and Chronic AR = Study Residue Value from Dosing at 100 ppm / 2000 X.

OPPTS GLN 860.1400: Magnitude of the Residue in Water, Fish, Irrigated Crops

CPM is not registered for use on potable water or aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics. [CPM is registered on rice strictly for post-harvest treatment of stored rice grain.]

OPPTS GLN 860.1460: Magnitude of the Residue in Food-handling Establishments

CPM is not registered for use in food-handling establishments; therefore, no residue chemistry data are required under these guideline topics.

OPPTS GLN 860.1850/1900: Confined/Field Accumulation in Rotational Crops

As CPM is restricted to use on stored grains and grain storage facilities, no residue chemistry data are required under these guideline topics.

ANTICIPATED RESIDUES FOR DIETARY RISK ASSESSMENT

Refinements such as anticipated residues (ARs) are a way to estimate actual exposures, as opposed to high-end estimates (i.e., tolerances). Monitoring data from the USDA Pesticide Data Program (PDP) are available. Out of 1,562 monitoring data samples from PDP (1995-1997) for wheat, 920 samples had detectable residues; see Table 5 for details. The wheat PDP residue values should be translated to the other supported RACs (barley, oats, rice and sorghum) because the use pattern of CPM is the same. Out of 1,297 monitoring data samples from PDP (1996-1997) for milk, none had detectable residues; see Table 6 for details. The PDP residue values should be used in the acute and chronic dietary exposure assessments.

In general, the FDA Surveillance Monitoring data (1992-1998) supported the percentage of detections found in wheat by PDP. When choosing which data set to use for a Monte Carlo assessment, the order of preference is generally PDP data > FDA data > field trial data. Monitoring data is preferred over field trial data because it is sampled longer after harvest and is therefore more reflective of residues consumed "at the dinner plate"; PDP data is preferred over FDA data because of the statistical design of the PDP program specific for dietary risk assessment

and because the foods are prepared before analysis as they would be at home (i.e. peeling, washing, etc.). Monitoring data can be "decomposed" prior to use in acute dietary risk assessment; however, this is not necessary for CPM because the raw agricultural commodities on which it is used on are considered "blended" commodities.

Table #5. Summary of Wheat PDP Data.

| Crop | Year | # of Samples Analyzed | # of Detects | % of Detects | Minimum Concentration (ppm) | Maximum Concentration (ppm) | Average Concentration (ppm) | LOD (ppm) |
|-------------|------|-----------------------|--------------|--------------|-----------------------------|-----------------------------|-----------------------------|-----------|
| Wheat | 1995 | 600 | 325 | 54 | 0.002 | 3.322 | 0.11 | 0.001 |
| Wheat | 1996 | 340 | 249 | 73 | 0.002 | 1.525 | 0.09 | 0.001 |
| Wheat grain | 1997 | 622 | 346 | 56 | 0.002 | 1.796 | 0.11 | 0.001 |
| Total | | 1562 | 920 | Ave. = 61% | | | | |

Table #6. Summary of Milk PDP Data.

| Crop | Year | # of Samples Analyzed | # of Detects | % of Detects | Minimum Concentration (ppm) | Maximum Concentration (ppm) | Average Concentration (ppm) | LOD Range (ppm) |
|-------|------|-----------------------|--------------|--------------|-----------------------------|-----------------------------|-----------------------------|-----------------|
| Milk | 1996 | 570 | 0 | 0 | 0 | 0 | 0 | 0.001-0.002 |
| Milk | 1997 | 727 | 0 | 0 | 0 | 0 | 0 | 0.001-0.002 |
| Total | | 1297 | 0 | 0 | | | | |

For the purposes of dietary risk assessment, acute and chronic ARs for CPM have been calculated for barley, oats, rice, sorghum, grain, meat, milk, poultry and eggs; see summary Table 7.

Table # 7. Acute and Chronic ARs for Dietary Risk Assessment.

| Commodity | Acute AR ¹ (ppm) | Chronic AR ² (ppm) | Processing Factor |
|-----------------------------|-----------------------------|-------------------------------|---------------------------|
| Barley, grain ³ | PDP Data | 0.06 | 2.1X for bran |
| Oats, grain ⁴ | PDP Data | 0.06 | 2.5 X hulls |
| Rice, grain ⁵ | PDP Data | 0.06 | 3.6 X hulls 1.8 X bran |
| Sorghum, grain ⁶ | PDP Data | 0.06 | N/A |

| Commodity | Acute AR ¹ (ppm) | Chronic AR ² (ppm) | Processing Factor |
|---|--------------------------------|----------------------------------|--|
| Wheat, grain ⁷ | PDP Data | 0.06 | 2.1 X bran, 3.2 X shorts 1.5 X reddog, 2.7 X germ |
| Fat of cattle, goats, hots, horses and sheep | 0.008 | 0.008 | N/A |
| Meat of cattle, goats, horses and sheep | 0.0001 | 0.0001 | N/A |
| Liver of cattle, goats, horses and sheep | 0.0001 | 0.0001 | N/A |
| Kidney of cattle, goats, horses and sheep | 0.0004 | 0.0004 | N/A |
| Hogs, fat | 0.007 | 0.007 | N/A |
| Hogs, muscle | 0.001 | 0.001 | N/A |
| Hogs, mbyyp | 0.00009 | 0.00009 | N/A |
| Milk | PDP Data | 0.0007 | N/A |
| Milk, fat | PDP Data | 0.0007 | N/A |
| Poultry, fat | 0.00004 | 0.00004 | N/A |
| Poultry, meat | 0.000005 | 0.000005 | N/A |
| Poultry, liver | 0.000005 | 0.000005 | N/A |
| Eggs | 0.00001 | 0.00001 | N/A |

¹ The acute dietary risk assessment should utilize the entire distribution of monitoring data (PDP) of CPM residue value detections with no further adjustment for percent of crop treated (% CT); ½ LOD should be used for non-detects. Processing factors should be incorporated where appropriate.

² The chronic dietary risk assessment should utilize the monitoring data (PDP) for the RAC incorporating ½ the LOD (for treated non-detects) to calculate the average residue. The chronic RAC ARs given here are the average residue value from the PDP data, incorporating ½ the LOD (the PDP LOD = 0.001 ppm for all 3 years). The chronic milk and milk fat ARs given here are the average residue values from the 1996-97 PDP data (all non-detectable residues, therefore ½ the average LOD was used [range= 0.001-0.002 ppm]). Processing factors should be incorporated. No further adjustment should be made for % CT.

³ The available processing study on barley does not provide residue data on pearled barley, flour or bran; however, data from the wheat processing study are translatable to barley.

⁴ Data on oat flour are not available; however, the wheat processing study indicates that residues of CPM *per se* do not concentrate in flour.

⁵ The available rice processing study indicates that residues of CPM *per se* do not concentrate in polished rice.

⁶ The sorghum processing study demonstrated that residues of CPM do not concentrate appreciably (1.4 X) in sorghum flour. Furthermore, flour is the only sorghum processed commodity currently regulated and is used exclusively in the U.S. as a component for drywall, and not as either a human food or livestock feed.

⁷ The available wheat processing study indicates that residues of CPM *per se* do not concentrate in flour.

Table A. Residue Chemistry Science Assessments for Reregistration of CPM.

| GLN: Data Requirements | Current Tolerances, ppm [40 CFR] | Must Additional Data Be Submitted? | References |
|---|-------------------------------------|------------------------------------|--|
| 860.1200: Directions for Use | N/A | Yes ¹ | See Section 860.1200 |
| 860.1300: Plant Metabolism | N/A | No | 00114290 ² |
| 860.1300: Animal Metabolism | N/A | No | 00114291 ² 00114292 ² 00114293 ² 00114294 ² |
| 860.1340: Residue Analytical Methods | | | |
| - Plant commodities | N/A | No | 00042611 ³ 00042612 ³ 00042618 ³ 42852701 ⁴ |
| - Animal commodities | N/A | No | 00042613 ³ 00042616 ³ 00042617 ³ |
| 860.1360: Multiresidue Methods | N/A | No | See p. 4; FDA Multiresidue Protocols D and E (PAM I Sections 232.4 and 211.1) |
| 860.1380: Storage Stability Data | N/A | Yes ⁵ | |
| 860.1500: Crop Field Trials | | | |
| <u>Cereal Grains Group</u> | | | |
| - Barley, grain | 6.0 [§180.419] | Yes ⁶ | 00042599 ³ |
| - Oats, grain | 6.0 [§180.419] | Yes ⁶ | 00042599 ³ |
| - Rice, grain | 6.0 [§180.419] | Yes ⁶ | 00042599 ³ |
| - Sorghum, grain | 6.0 [§180.419] | Yes ⁶ | 00042599 ³ |
| - Wheat, grain | 6.0 [§180.419] | Yes ⁶ | 00042599 ³ |
| <u>Miscellaneous Commodities</u> | | | |
| - Aspirated Grain Fractions | None | Yes ⁷ | 42017101 ⁸ |
| 860.1520: Processed Food/Feed | | | |
| - Barley, milled fractions (exc. flour) | 90.0 [§185.1050] [§186.1050] | No | 00042607 ³ |
| - Oats, milled fractions (exc. flour) | 130.0 [§185.1050] [§186.1050] | No | 00042606 ³ |

| GLN: Data Requirements | Current Tolerances, ppm [40 CFR] | Must Additional Data Be Submitted? | References |
|--|--|--|--|
| - Rice, milled fractions (exc. flour) | 30.0 [§185.1050] [§186.1050] | No | 00042609 ³ 00042610 ³ |
| - Sorghum, milled fractions (exc. flour) | 90.0 [§185.1050] [§186.1050] | No | 00042604 ³ |
| - Wheat, milled fractions (exc. flour) | 30.0 [§185.1050] [§186.1050] | No | 00042608 ³ |
| 860.1480: Meat, Milk, Poultry, and Eggs | | | |
| - Meat, Meat-by-products, and fat of cattle, goats, hogs, horses, and sheep | 0.5 [§180.419] | No | 00042596 ³ 00042600 ³ 00042601 ³ |
| - Milk | 0.05 [§180.419] | No | 00042603 ³ |
| - Milk, fat | 1.25 [§180.419] | No | 00042603 ³ |
| - Meat and Meat-by-products of poultry | 0.5 [§180.419] | No | 00042602 ³ |
| - Eggs | 0.1 [§180.419] | No | 00042602 ³ |
| 860.1400: Water, Fish, and Irrigated Crops | None | No | |
| 860.1460: Food Handling | None | N/A | |
| 860.1850: Confined Rotational Crops | N/A | N/A | |
| 860.1900: Field Rotational Crops | None | N/A | |

1. Based upon the available residue data and/or changes in data requirements, the Agency is recommending changes to use directions. The recommended label amendments are listed in the SUMMARY OF SCIENCE FINDINGS, under Directions for Use.
2. PP#0F2423 and /FAP#0H5277, DP Barcode [None], R. Perfetti, 1/25/83
3. PP#0F2423 and /FAP#0H5277, DP Barcode [None], R. Perfetti, 3/13/81
4. DP Barcode D193346, M. Flood, 3/10/94
5. Sample storage intervals and conditions for the residue trials on stored grains, processed commodities, and livestock are required. If the samples were analyzed ≥ 30 days after collection, supporting storage stability data are required. Storage stability data submitted for chlorpyrifos reregistration suggest that residues of CPM are probably stable frozen in plant and animal matrices; however, confirmatory data on CPM that support the storage

intervals and conditions of the residue studies are required.

6. Confirmatory data supporting the results of the original residue studies on stored grains are required. Data are needed from three studies depicting residues of CPM in/on wheat grain stored in CPM-treated storage facilities and sampled on the day of treatment after application at the maximum use rate. The trials should reflect the use of both water and mineral oils as the spray diluent. If the samples are stored frozen for >30 days prior to analysis, the residue studies should be accompanied by supporting storage stability data.
7. Data are required depicting CPM residues in/on aspirated grain fractions (grain dust) derived from wheat and sorghum grain treated with CPM. RAC samples should be treated using both water and mineral oil as diluents. Adequate corn grain dust data are available indicating that CPM residues in/on corn grain dust were 84x higher than in/on corn grain.
8. PP#6F3429, CBTS No. 11149, DP Barcode D169228, J. Morales, 4/30/92.

TOLERANCE REASSESSMENT SUMMARY

Tolerances for CPM residues are currently expressed as the combined residues of CPM and TCP in or on plant and animal commodities [40 CFR §180.419]. HED has concluded that the U.S. tolerance expression should be amended to include only CPM *per se* (M. Flood, 4/29/91). Accordingly, the tolerance definition for CPM should be amended to include only parent CPM. In addition, the food and feed additive tolerances for *grain milled fractions (exc. flour)* listed separately under 40 CFR §185.1050 and §186.1050 should be revoked concomitant to establishing the appropriate tolerances, noted below, for residues of CPM in processed commodities under 40 CFR §180.419.

A summary of the CPM tolerance reassessment for the above commodities and recommended modifications in commodity definitions are presented in Table B.

Tolerances Listed Under 40 CFR §180.419:

Provided that (i) the requested label amendments are made, (ii) questions concerning the storage stability of CPM are resolved, and (iii) confirmatory residue data on stored grains are submitted, sufficient data are available to reassess tolerances for CPM residues in/on barley, oats, rice, sorghum, and wheat. The established tolerances are adequate for CPM residues in/on stored grains of barley, oats, rice, sorghum and wheat.

Provided that storage stability concerns are addressed, sufficient data are available to reassess tolerances for CPM residues in poultry tissue and eggs. Based on the dietary burden for poultry (6.0 ppm), and data from poultry feeding and metabolism studies, the established tolerances for residues of CPM in poultry should be lowered to 0.01 ppm in muscle, mbyp, and eggs, and 0.05 ppm in fat.

Sufficient data are available for a risk assessment on residues of CPM in cattle, goats, hogs, horses, and sheep commodities. However, the tolerances cannot be reassessed at this time because residue data on aspirated grain fractions derived from treated wheat and sorghum are required. Data from the available corn processing study indicate that a tolerance of at least 400 ppm will be needed for residues of CPM in aspirated grain fractions (the dietary burdens noted for cattle and swine include this contribution). If significantly higher residues are found in wheat or sorghum aspirated grain fractions, a new ruminant feeding study may be required.

The dietary burden for beef and dairy cattle (100 ppm) and the data from the ruminant feeding study support increasing the tolerances for CPM residues in fat of cattle, horses, goats, and sheep to 1.0 ppm, and lowering the tolerances for CPM residues in meat and mbyp to 0.05 ppm. The available data indicate that established tolerances for milk and milkfat are adequate.

Based on the dietary burden for swine of 85 ppm, the data from the hog feeding study support increasing the tolerance for residues in fat to 1.0 ppm, and lowering the tolerances for residues in meat and mby to 0.15 ppm and 0.05 ppm, respectively.

Tolerances Listed Under 40 CFR §185.1050 and §186.1050 :

Tolerances for residues of CPM in milled fractions (excluding flour) of barley, oats, rice, sorghum, and wheat should be revoked concomitant with establishing separate tolerances for residues in the appropriate processed commodities under 40 CFR §180.419 (see next section).

Tolerances Needed Under 40 CFR §180.419:

New tolerances are needed for CPM residues in/on aspirated grain fractions. A tolerance of at least 400 ppm will be required for CPM residues in/on aspirated grain fractions, based upon the 84x concentration factor and current HAFT residues of 4.3 ppm in/on corn grain. However, this tolerance cannot be assessed until aspirated grain fraction data on sorghum and wheat are available.

A tolerance of 15.0 ppm is required for CPM residues in barley bran based upon the 2.1x concentration factor (translated from wheat) and HAFT residues of 5.4 ppm in/on barley grain.

Based on a 2.5x concentration factor and HAFT residues of 5.2 ppm for stored oat grain, a tolerance of 15 ppm should be established for residues of CPM *per se* in oat hulls.

Tolerances for residues of CPM *per se* should be established at 25 ppm in rice hulls and 15 ppm in rice bran based on average concentration factors of 3.6x and 1.8x, respectively, and HAFT residues of 6.0 ppm.

Based on the concentration factors of 2.1x in bran, 3.2x in shorts, 1.5x in reddog flour, and 2.7x in germ, and HAFT residues of 5.5 ppm in/on wheat grain, a tolerance for residues of CPM *per se* should be established in wheat milled fractions (excluding flour) at 20 ppm.

Once the necessary separate tolerances are established for residues in processed commodities, the feed/food additive tolerances for residues in milled fractions (exc. flour) of barley, oats, and wheat under §185.1050 and §186.1050 should be revoked. As residue data on sorghum processed fractions are no longer required, the tolerance for residues in sorghum milled fractions should also be revoked.

Table B. Tolerance Reassessment Summary for CPM.

| Commodity | Current Tolerance (ppm) | Tolerance Reassessment (ppm) | Comment/ <i>Correct Commodity Definition</i> |
|--|-------------------------|------------------------------|--|
| Tolerances listed under 40 CFR §180.419: | | | |
| Barley, grain | 6.0 | 6.0 | |
| Oats, grain | 6.0 | 6.0 | |
| Rice, grain | 6.0 | 6.0 | |
| Sorghum, grain | 6.0 | 6.0 | |
| Wheat, grain | 6.0 | 6.0 | |
| Fat of cattle, goats, hogs, horses, & sheep | 0.5 | TBD ^{a,b} | Residue data indicate that the tolerance for residues in fat should be increased to 1.0 ppm |
| Meat and mby of cattle, goats, horses, & sheep | 0.5 | | Residue data support lowering the tolerance for residues of CPM <i>per se</i> in muscle and mby to 0.05 and 0.15 ppm, respectively. |
| Hogs, muscle | 0.5 | | Residue data support lowering the tolerance for residues in muscle and mby to 0.15 and 0.05 ppm, respectively. |
| Hogs, mby | 0.5 | | |
| Milk | 0.05 | | |
| Milk, fat | 1.25 | | |
| Poultry, fat | 0.5 | 0.05 | Residue data support lowering the tolerances established on poultry commodities. |
| Poultry, mby | 0.5 | 0.01 | |
| Poultry, meat | 0.5 | 0.01 | |
| Eggs | 0.1 | 0.01 | |
| Tolerances listed under 40 CFR §185 and §186.1050: | | | |
| Barley, milled fractions (excluding flour) | 90.0 | Revoke | Tolerance should be revoked concomitant with establishing a 15 ppm tolerance on <i>barley bran</i> . |
| Oats, milled fractions (excluding flour) | 130.0 | | Tolerance should be revoked concomitant with establishing a 15 ppm tolerance on <i>oat hulls</i> . |
| Rice, milled fractions (excluding flour) | 30.0 | | Tolerance should be revoked concomitant with establishing tolerances on <i>rice hulls</i> (25 ppm) and <i>bran</i> (15 ppm). |
| Sorghum, milled fractions (excluding flour) | 90.0 | | Tolerance should be revoked. There are no longer any processed commodities of grain sorghum considered as food for humans or feed for livestock. |
| Wheat, milled fractions (excluding flour) | 30.0 | | Tolerance should be revoked concomitant with establishing a tolerance on <i>wheat milled fractions (exc. flour)</i> at 20 ppm. |

| Commodity | Current Tolerance (ppm) | Tolerance Reassessment (ppm) | Comment/ <i>Correct Commodity Definition</i> |
|--|-------------------------|------------------------------|---|
| Tolerances needed under 40 CFR §180.419 | | | |
| Aspirated Grain Fractions | None | TBD | The available data on corn support a tolerance of <u>at least</u> 400 ppm. Additional data are required for sorghum and wheat |
| Barley, bran | 90.0 | 15.0 | Concomitant with revoking the tolerance for barley milled fractions, a tolerance on <i>barley bran</i> should be established |
| Oats, hulls | 130.0 | 15.0 | Concomitant with revoking the tolerance for oat milled fractions, a tolerance on <i>oat hulls</i> should be established. |
| Rice, hulls | 30.0 | 25.0 | Concomitant with revoking the tolerance for rice milled fractions, a tolerance on <i>rice hulls</i> should be established. |
| Rice, bran | 30.0 | 15.0 | Concomitant with revoking the tolerance for rice milled fractions, a tolerance on <i>rice bran</i> should be established. |
| Wheat milled fractions (excluding flour) | 30.0 | 20.0 | Concomitant with revoking the food/feed additive tolerance for wheat milled fractions, a tolerance on <i>wheat milled fractions (exc. flour)</i> should be established. |

^a TBD = To be determined. Tolerance cannot be determined at this time because additional data are required.

^b The tolerances cannot be reassessed at this time because residue data on aspirated grain fractions derived from treated wheat and sorghum are required. Aspirated grain fractions contribute significantly to the dietary burden for cattle and swine. If significantly higher residues are found in wheat or sorghum aspirated grain fractions, a new ruminant feeding study may be required.

CODEX HARMONIZATION

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for CPM residues in/on various plant and animal commodities. The Codex MRLs and U.S. tolerances are not compatible because the U.S. tolerance expression currently includes the parent CPM and its metabolite, TCP. However, HED has recommended that the U.S. tolerance expression be amended to include only CPM (M. Flood, 4/29/91). Once the U.S. tolerance definition is amended, it will be compatible with the definition for Codex MRLs.

A comparison of the Codex MRLs (from *Guide to Codex Maximum Limits for Pesticide Residues*, Updated 4/99) and the corresponding U.S. tolerances is presented in Table C. The following conclusions can be made regarding efforts to harmonize the U.S. tolerances with the Codex MRLs:

Once the U.S. tolerance definition is amended to include only CPM, U.S. tolerances and Codex MRLs would be compatible for wheat bran, meat and edible offal of cattle, meat and edible offal of chicken, and eggs.

Based upon the use patterns registered in the U.S. and the available residue data, compatibility of U.S. tolerances and Codex MRLs is not currently possible for the following crops/commodities: barley, cattle fat, chicken fat, milk, oats, rice, sorghum, wheat and wheat processed commodities (except bran). Codex has postponed discussion on MRLs for cereal commodities pending review of additional residue data on these commodities.

Table C. Codex MRLs for chlorpyrifos-methyl and applicable U.S. tolerances.

| Codex | | | Reassessed U.S. Tolerance (ppm) | Recommendation and Comments |
|---------------------------|-------------------|----------------|------------------------------------|--|
| Commodity (As Defined) | MRL (mg/kg) | Step | | |
| Apple | 0.05 | CXL | None | Not registered for this use in the U.S. |
| Artichoke globe | 0.1 | CXL | | |
| Barley | 10.0 ^a | 6 ^b | 6.0 | U.S. residue data indicate that the lower tolerance is adequate. Use pattern in U.S. specifies to apply up to 6.0 ppm. |
| Cabbages, Head | 0.1 | CXL | None | Not registered for this use in the U.S. |
| Cattle fat | 0.05 | CXL | 0.5 | Data for aspirated grain fractions are required before US tolerance can be reassessed |
| Cattle, meat | 0.05 | CXL | 0.5 | Data for aspirated grain fractions are required before US tolerance can be reassessed |
| Cattle, Edible offal of | 0.05 | CXL | 0.5 | U.S. tolerance is for <i>meat byproducts</i> . Data for aspirated grain fractions are required before US tolerance can be reassessed |
| Chicken, fat | 0.05 | CXL | 0.05 | |
| Chicken, meat | 0.05 | CXL | 0.01 | U.S. residue data support lower tolerance. |
| Chicken, Edible offal of | 0.05 | CXL | 0.01 | U.S. tolerance is for <i>meat byproducts</i> . U.S. residue data support lower tolerance. |
| Chinese cabbage | 0.1 | CXL | None | Not registered for these uses in the U.S. |
| Common bean | 0.1 | CXL | | |
| Date | 0.05 | CXL | | |
| Egg plant | 0.1 | CXL | | |
| Eggs | 0.05 | CXL | 0.01 | U.S. residue data support lower tolerance. |
| Grapes | 0.2 | CXL | None | Not registered for these uses in the U.S. |
| Lettuce, Head | 0.1 | CXL | | |
| Milk | 0.01 ^c | CXL | 0.05 | Data for aspirated grain fractions are required before US tolerance can be reassessed |
| Mushrooms | 0.01 ^c | CXL | None | Not registered for this use in the U.S. |
| Oats | 10.0 ^a | 6 ^b | 6.0 | U.S. residue data indicate that the lower tolerance is adequate. Use pattern in U.S. specifies to apply up to 6.0 ppm. |
| Oranges, Sweet, Sour | 0.5 | CXL | None | Not registered for these uses in the U.S. |
| Peach | 0.5 | CXL | | |
| Peppers | 0.5 | CXL | | |
| Radish | 0.1 | CXL | | |
| Rice | 0.1 | CXL | | |

Table C. Continued.

| Codex | | | Reassessed U.S. Tolerance (ppm) | Recommendation and Comments |
|---------------------------|-------------------|-------------------|------------------------------------|--|
| Commodity (As Defined) | MRL (mg/kg) | Step | | |
| Rice | 10.0 ^a | 6(a) ^b | 6.0 | U.S. residue data indicate that the lower tolerance is adequate. Use pattern in U.S. specifies to apply up to 6.0 ppm. |
| Sorghum | 10.0 ^a | CXL | 6.0 | U.S. residue data indicate that the lower tolerance is adequate. Use pattern in U.S. specifies to apply up to 6.0 ppm. |
| Tea, Green, Black | 0.1 | CXL | None | Not registered for these uses in the U.S. |
| Tomato | 0.5 | CXL | | |
| Wheat | 10.0 ^a | CXL | 6.0 | U.S. residue data indicate that the lower tolerance is adequate. Use pattern in U.S. specifies to apply up to 6.0 ppm. |
| Wheat bran, Unprocessed | 20.0 ^d | CXL | 20.0 | |
| Wheat flour | 2.0 ^a | CXL | None | U.S. residue data indicate that a separate tolerance for wheat flour is not required. |
| White bread | 0.5 ^d | CXL | None | Not a regulated commodity in the U.S. |
| Wholemeal bread | 2.0 ^d | CXL | None | Not a regulated commodity in the U.S. |

^a Accommodates post-harvest treatment of commodity.

^b Codex discussions on MRLs for cereal commodities have been postponed pending review of all residue and processing studies available on cereal commodities and estimation of IEDIs.

^c MRL set at or about the limit of determination.

^d Accommodates post-harvest treatment of the primary food commodity.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

DP Barcode: None
Subject: PP#0F2423/0H5277. Chlorpyrifos-methyl on Grains. Evaluation of Analytical Methods and Residue Data.
From: R. Perfetti
To: J. Ellenberger
Dated: 3/13/81
MRID(s): None cited

DP Barcode: None
Subject: PP#0F2423/0H5277. Chlorpyrifos-methyl on Stored Grains.
From: R. Perfetti
To: J. Ellenberger
Dated: 1/25/83
MRID(s): None cited

DP Barcode: None
Subject: Clarification of Chlorpyrifos Reregistration Standard - Revision to Exclude TCP Metabolite from Existing Tolerances.
From: E. Doyle
To: R. Schmitt
Dated: 4/1/91
MRID(s): None

CBTS No.: 6969
DP Barcode: None
Subject: PP#6F3429/6H5506 Chlorpyrifos-methyl in/on Stored Grain. Amendment to Remove TCP from Tolerance Expression.
From: M. Flood
To: D. Edwards
Dated: 4/29/91
MRID(s): None

CBTS No.: 11149
DP Barcode: D169228
Subject: PP#6F3429. Chlorpyrifos-methyl on Corn Dust. Amendment of 8/18/86.
From: J. Morales
To: D. Edwards
Dated: 4/30/92
MRID(s): 42017101

DP Barcode: D186441
Subject: 6F3429/6H5506: Chlorpyrifos-methyl on corn grain. Amendment in response to review of 4/30/92.
From: J. Morales
To: D. Edwards/C. Andreasen
Dated: 6/2/93
MRID(s): None

DP Barcode: D193346
Subject: 6F3429/6H5506: Chlorpyrifos-methyl in Stored Grain. Independent Lab Validation of Test Kit.
From: M. Flood
To: D. Edwards/C. Andreasen
Dated: 3/10/94
MRID(s): 42852701

CBTS No.: 130810
DP Barcode: D200683
Subject: 6F3429/6H5506: Chlorpyrifos-methyl (Reldan 4E®) in/on Stored Corn Grain. Results of EPA Method Validation.
From: M. Flood
To: D. Edwards/C. Andreasen
Dated: 6/15/94
MRID(s): None

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00042596 Smith, G.N.; Taylor, Y.S.; Watson, B.S. (1970) An Analytical Method for the Determination of 3,5,6-Trichloro-2-pyridinol in Animal Tissues and the Metabolism of the Pyridinol in Rats: OL 3132. Method dated Jul 30, 1970. (Unpublished study received Sep 18, 1980 under 464-557; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:099644-B)

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